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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,159	08/10/2001	Michael Schreiber	35-213	3633

7590 10/02/2003

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/02/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,159

Applicant(s)

SCHREIBER, MICHAEL

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1- 54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

This communication is response to paper #16, filed 4 June 2003.

Upon further consideration the restriction requirement has been changed to more correctly reflect the patentably distinct inventions in the claims. The Office regrets any inconvenience to Applicant.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1- 3, 23- 25, 47, and 54, drawn to a protein mixture and vaccine.

Group II, claim(s) 4- 8, 26, 49, and 50- 52, drawn to DNA vaccine.

Group III, claim(s) 9- 12, 27, 28, drawn to a nucleic acid sequence.
If Applicant elects this group, they must elect one SEQ ID# for examination.

Group IV, claim(s) 13, drawn to a nucleic acid sequence of SEQ ID #11.

Group V, claim(s) 14- 18, 28, drawn to a nucleic acid sequence of SEQ ID #12, it's complement, or modifications of SEQ ID#12.

Group VI, claim(s) 19- 22, drawn to a double stranded nucleic acid mixture comprising of SEQ ID #11 or SEQ ID#1 or modifications of those SEQ ID #.
If Applicant elects this group, they must elect one SEQ ID# for examination.

Group VII, claim(s) 29, drawn to an expression vector.

Group VIII, claim(s) 30- 37, drawn to a vector mixture.
If Applicant elects this group, they must elect one SEQ ID# for examination.

Group IX, claim(s) 38- 40, drawn to a process for preparation of nucleic acid.

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Group X, claim(s) 41- 43, drawn to a process for preparation of a vector mixture.

Group XI, claim(s) 44, 46, 47 drawn to a process for preparation of a protein vaccine.

Group XII, claim(s) 45, 48, 49, drawn to a process for preparation of a DNA vaccine.

Group XIII, claims 53- 54, drawn to a pharmaceutical composition made of DNA and protein.

The inventions listed as Groups I to XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I is directed to a vaccine comprising at least 100 variant proteins, which is the first product. However, because Tartar et al. (FR 2677363, abstract, from IDS) teaches a vaccine composition that represents more than 100 epitope variants of a virus protein, no special technical feature exists for Group I as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. It is noted that claim 1 requires only a mixture of viral protein molecules, characterized in that the sequence variants are of a single viral protein. The technical features of Groups II-X, XII, and XIII are drawn to methods or products having different starting materials, which do not require each other for their practice and do not share the same or a corresponding technical feature. Invention XI is a method of making the protein vaccine; however, because unity is lacking, it is proper to separate methods of making and using from the product claims. Note that PCT Rule 13 does not provide for multiple products or methods within a single application. Because the technical feature of Group I is not a

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special technical feature, and because the technical features of the Group II-X, XII, and XIII inventions are not present in the Group I claims, unity of invention is lacking.

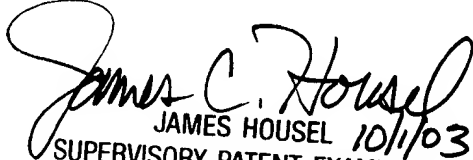
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). This includes election of specific SEQ ID# where required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Myron G. Hill
Patent Examiner
September 30, 2003


JAMES HOUSEL 10/1/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600